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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,565 | 10/17/2001 | Thomas J. Gardella | 0609.4730000 | 4604 |

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| HUNNICUTT, RACHEL KAPUST | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/869,565 | GARDELLA ET AL. | |
| | Examiner | Art Unit | |
| | Rachel K. Hunnicutt | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## RESPONSE TO AMENDMENT

Applicant's amendment filed September 20, 2004 is acknowledged. Claims 1-19 and 21 have been canceled. Claims 20 and 24-26 are amended. Claims 27 and 28 are new. Claims 20 and 22-28 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### *Claim Rejections/Objections Withdrawn*

The objection to the disclosure regarding Figure 1 containing amino acid and/or nucleic acid sequences is withdrawn in response to Applicant's amendment to the specification.

The rejection of claims 20 and 22-26 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in response to Applicant's amendments to the claims. The rejection of claims 19 and 21 is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 20 and 22-26 under 35 U.S.C. 112, second paragraph, regarding measuring a "biological response" is withdrawn in response to Applicant's amendments to the claims. The rejection of claim 19 is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claims 20 and 22-26 under 35 U.S.C. 112, first paragraph, for not being enabled for measuring any biological response, is withdrawn in response to Applicant's amendments to the claims. The rejection of claim 19 is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claim 21 under 35 U.S.C. 112, first paragraph, for not being enabled regarding novel biological materials, is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claims 20 and 22-24 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,494,806 is withdrawn in response to Applicant's amendments to the claims. The '806 patent does not anticipate a receptor comprising a deletion of the extracellular amino-terminal ligand binding domain. The rejection of claims 19 and 21 under 35 U.S.C. 102(b) is withdrawn in response to the cancellation of these claims.

The rejection of claim 19 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,495,662 is withdrawn in response to Applicant's cancellation of the claim.

***Claim Rejections Maintained/New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The rejection of claims 20 and 22-26 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record on p. 4-5 of paper no. 0504 and is applied to new claims 27-28.

Applicants have indicated that the cDNA clone was deposited on December 28, 1999. Applicants also have indicated that the materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. However, Applicants have not stated that the deposit will be replaced if it should ever become unviable. Applicants must provide assurance by an affidavit or declaration that the deposit will be maintained and that it will be replaced if it should ever become unviable.

The rejection of claims 20-24 under 35 U.S.C. 112, first paragraph, as not being enabled for agonists or antagonists of polypeptides that are 95% identical to SEQ ID NO: 2 is maintained for reasons of record on p. 7-8 of paper no. 0504 and is applied to new claims 27-28.

Applicants argue that the phrase "wherein said polypeptide has substantially identical structure and function to the structure and function of a rδNt receptor" sufficiently characterizes polypeptides which are 95% identical to SEQ ID NO: 2.

Applicants' arguments have been fully considered but have not been found to be persuasive. The only functions taught by the specification for the rδNt receptor are (1) binding PTH and PTH-related peptide; and (2) increasing cAMP levels when activated by PTH or PTH-related peptide. One skilled in the art would not know any other function of a rδNt receptor. Neither the art nor the specification teach any other functions for the rδNt receptor. Other functions may be associated with the rδNt receptor, but they have yet to be identified. The only way one of skill in the art could practice the claimed invention would be if the polypeptides in the methods increase intracellular cAMP levels when activated.

The rejection of claims 20-24 under 35 U.S.C. 112, first paragraph, as not complying with the written description requirement, is maintained for reasons of record on p. 8-9 of paper no. 0504.

Applicants argue that the specification teaches the types of substitutions that can be made in the rδNt receptor such that the polypeptide will be substantially similar in function to the polypeptide of SEQ ID NO: 2 (p. 18).

Applicants' arguments have been fully considered but have not been found to be persuasive. As stated above, the only functions taught by the specification for the rδNt receptor are (1) binding PTH and PTH-related peptide; and (2) increasing cAMP levels when activated by PTH or PTH-related peptide. One skilled in the art could make substitutions in SEQ ID NO: 2 such that it would still increase cAMP levels when activated, but the specification does not teach one skilled in the art how to make substitutions in SEQ ID NO: 2 that function differently. The specification does not teach that the only function of the rδNt receptor is increasing cAMP levels when activated by PTH or PTH-related peptide. Rather, it is only one known function of the rδNt receptor. One of skill in the art would not think that Applicants were in possession of variants of SEQ ID NO: 2 that functioned differently.

Claims 20 and 22-28 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20 and 22-28 refer to an "extracellular amino-terminal ligand binding domain having an amino acid sequence from about 26 to about 181 in

wild-type PTH receptor". It is not clear whether the deleted domain is the region spanning from residue 26 to residue 181 or whether 26 residues to 181 residues are deleted. The rejection could be obviated by amending the claim to read "from about residue 26 to about residue 181".

Claims 20, 22-24, and 27-28 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims encompass methods of screening for an agonist or an antagonist of PTH receptor activity by contacting cells expressing polypeptides at least 95% identical to SEQ ID NO: 2 with a test compound. However, the polypeptide "comprises a deletion of the extracellular amino-terminal ligand binding domain of a PTH-1 receptor, said extracellular amino-terminal ligand binding domain having an amino acid sequence from about 26 to about 181 in wild-type PTH receptor". If applicants mean a deletion spanning residue 26 to residue 181, it is impossible for a polypeptide to have this deletion and be 95% identical to SEQ ID NO: 2.

***Conclusion***

NO CLAIMS ARE ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
12/9/04

JANET ANDRES
PRIMARY EXAMINER